SUPPORTING STATEMENT FOR

FOOD CANNING ESTABLISHMENT REGISTRATION, PROCESS FILING AND RECORD KEEPING FOR ACIDIFIED FOODS AND THERMALLY PROCESSED FOODS IN HERMETICALLY SEALED CONTAINERS

OMB Control No. 0910-0037

A. Justification

1. Necessity for the Information Collection

According to the Federal Food, Drug and Cosmetic Act (the act), it is unlawful to introduce into interstate commerce food products that may be injurious to health or that are otherwise adulterated. Under the authority of Section 404 (Attachment A) of the act (21 U.S.C. 344), FDA promulgated regulations (21 CFR 108.25(a) and 108.35(a)) that require low-acid and acidified food processing establishments to register their firms, file scheduled process information, maintain records of processing and production records, and fulfill the mandatory provisions of the Good Manufacturing Practices (21 CFR 113 and 114) (Attachment B). The requirements are intended to ensure risk to public health does not increase from improper or inadequate manufacture, processing and packing of such foods, and to permit FDA to verify that appropriate procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *Clostridium botulinum* must be destroyed or inhibited to avoid production of the deadly toxin which causes botulism. This is accomplished with good manufacturing practices including the use of adequate heat processes and/or other means of preservation.

FDA regulations (21 CFR §§ 108.25(c)(1) and 108.35(c)(1)) require each firm that manufactures, processes or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce to register the establishment with the Food and Drug Administration using Form FDA 2541 (Attachment C). Federal regulations (21 CFR §§ 108.25(c)(2), 108.35(c)(2)) require each firm to provide data on the processes used to produce these foods using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers. Plant registration and process filing may be accomplished simultaneously. Subsequent to the original filing, firms are required to file only intentional changes basic to the adequacy of the scheduled process (21 CFR §§ 108.25(c)(2)(ii), 108.35(c)(2)(ii))).

In addition, 21 CFR §§ 108.25(g) and 108.35(h) require commercial processors to prepare, review and retain for three years all records of processing, deviations in

processing, container closure inspections and other records specified in the Good Manufacturing Practices. Records must be made available to FDA on request. Firms are also required to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (21 CFR §§ 108.25(d), 108.35(d)and(e)); and to develop and keep on file plans for recalling products that may endanger the public health (21 CFR §§ 108.25(e), 108.35(f)).

We are requesting OMB's approval of the following specific citations:

21 CFR 108.25(c)(1) - Reporting (Establishment Registration)

Commercial processors file information on each establishment engaged in processing acidified foods not later than 10 days from start-up.

21 CFR 108.25(c)(2) - Reporting (Process Filing)

Provide information on the scheduled processes before packing any new acidified food product not later than 60 days after registration.

21 CFR 108.25(d) - Reporting

Requires packers to report any instance of potential health endangering significance wherein the food has entered distribution in interstate commerce.

21 CFR 108.25 (e) - Record keeping

Requires processors of acidified foods to develop and keep on file plans for recalling products that may endanger the public health.

21 CFR 108.25(g) - Record keeping

Requires packers to prepare, review, and retain all production records for 3 years from date of manufacture.

21 CFR 108.35(c)(1) - Reporting (Establishment registration)

Commercial processors file information on each establishment engaged in processing low-acid foods not later than 10 days from start-up.

21 CFR 108.35(c)(2) - Reporting (Process Filing)

Provide information on the scheduled processes for low-acid foods prior to packing

any new product.

21 CFR 108.35(c)(2)(ii) - Reporting (Process Filing)

Intentionally modified process shall be substantiated as to its adequacy and recorded in writing in the packer's files prior to its use and to report process changes to FDA within 30 days after first use.

21 CFR 108.35(c)(2)(ii) - Record keeping

Requires packer to record and file full information on any change of a previously filed scheduled process.

21 CFR 108.35(d) - Reporting

Requires packers to report any instance of spoilage or process deviation the nature of which indicates potential health significance wherein the food has entered distribution.

21 CFR 108.35(e) - Reporting

Requires packer to report any instance wherein such food, which may be injurious to health because of microbial contamination, has entered distribution.

21 CFR 108.35(f) - Record keeping

Requires processors of thermally processed low-acid foods sealed in hermetically sealed containers develop and keep on file plans for recalling products that may endanger the public health.

21 CFR 108.35(h) - Record keeping

Requires a commercial processor to prepare, review, and retain all records of processing, processing deviations, container closure inspections, and other records for a period of 3 years.

21 CFR 113.60(c)- Disclosure (Language approval only)

Requires thermally processed low-acid foods in hermetically sealed containers be marked with an identifying code to permit lots to be traced after distribution.

21 CFR 113.83 - Record keeping

Requires preparation and permanent retention of complete records covering process establishment by the person or organization establishing the process.

21 CFR 113.87(a) - Record keeping/Disclosure

Requires that process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator.

21 CFR 113.89 - Record keeping

Requires a record of evaluation procedures used for process deviation evaluations for thermally processed low-acid foods; a separate file or log identifying process deviations, and the actions taken.

21 CFR 113.100 - Record keeping

Specifies processing and production information to be observed and recorded by retort or processing operator.

21 CFR 114.80(b) - Disclosure (Language approval only)

Requires acidified foods be marked with an identifying code to permit lots to be traced after distribution.

21 CFR 114.89 - Record keeping

Retention of records of procedures and results of evaluating acidified finished food products for potential hazard to public health.

21 CFR 114.100(a) through (d) - Record keeping

Specifies three year retention of records and reports dealing with production processes and controls.

We are also requesting OMB approval of the following forms:

> Form FDA 2541, Food Canning Establishment Registration (21 CFR 108.25(c)(1) and 108.35(c)(1)). (Attachment C)
>
> Form FDA 2541a, Food Canning Establishment Process Filing Form For All Methods Except Aseptic (21 CFR 108.25(c)(2) and 108.35(c)(2)). (Attachment D)

Form FDA 2541c, Food Process Filing For Low-Acid Aseptic Systems (21 CFR 108.35(c)(2)). (Attachment E)

2. Uses of the Information

The records of processing information are periodically reviewed during factory inspections by FDA field investigators and Center personnel to verify fulfillment of the requirements in 21 CFR 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

3. Use of Improved Information Technology

FDA management of acidified foods and thermally processed low-acid foods establishments, registration and process filing is achieved through receipt of completed forms. Previously, information has been keyed into a computerized data entry and retrieval system. In an effort to facilitate the registration and filing requirement, FDA developed an electronic system to permit registration and filing over the Internet. This system is part of FDA's significant investments in the plan for meeting GPEA goals. The electronic submission capability of the Low Acid Canned Food (LACF) Program titled *eLACF* is the second major registration application to be support by and integrated under the new FDA Unified Registration and Listing System (FURLs). This meets a major milestone in the Agency's plan to provide one place (FURLS) for industry to access multiple registration systems. As a result of the implementation of an electronic submission capability for the LACF Program, we anticipate a significant decrease in the annual burden hours to the respondents and cost to the Government. However, since this is a new initiative, actual burden reduction changes to the respondents and to the Government will become available no sooner than the end of FY 2005.

Full deployment and use of the Web-based Internet system for domestic firms was completed in December, 2004, while full deployment and use for foreign firms is estimated to be June, 2005. Currently, the domestic industry has 1,317 firms registered in the LACF Program and 261 of them are using the electronic submission capability of the eLACF system. From December 2004 to May 2005, approximately 1,630 domestic process filing forms were submitted electronically and 1,059 were submitted non-electronically. In April 2005, we began deployment of the eLACF system to foreign industry. There are currently 6,757 foreign firms registered in the LACF Program and 55 of these foreign firms are using the electronic submission capability of the eLACF system. From December 2004 to May 2005, approximately 123 foreign process filing forms were submitted electronically and 6,446 foreign process filing forms were submitted non-electronically.

In that the system has built in logic, it would greatly eliminate the submission of erroneous data and further eliminate the attempted filing of processing information for products that are excluded from the filing requirements of the regulations. This could reduce the amount of submissions by another 3% - 8%. This would significantly reduce the amount of time for the technical review of processing data.

The information recorded on processing records, by industry, is the primary means whereby the safety and freedom from adulteration of acidified foods and thermally processed low-acid foods in hermetically sealed containers may be assured. The recorded information is specific to each commercial processor and can only be generated by that establishment. It is not of a general nature and is not available in libraries and academia. Any use of improved technology appropriate to satisfy the requirements is acceptable to FDA

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4. Efforts to Avoid Duplication and Unavailability of Similar Information

The data submitted are specific to the individual food processing establishments. No other regulation or information collection duplicates this effort.

The need for recording procedures was realized and initiated by the industry. Prior to record keeping becoming mandatory, the procedures were reviewed to avoid duplication. Most would be unique to each manufacturer.

The information collected is available only from the individual food processing establishments and remains current unless canceled or replaced by the firms.

5. Methods to Minimize Burden on Small Businesses

The information collected is of a regulatory nature and the requirements are the same for small or large food processing establishments. However, FDA does help small businesses in dealing with regulatory requirements through the Office of Small Manufacturers Assistance.

6. Consequences if Data Were Collected Less Frequently

Commercial processors engaging in the manufacture, processing, or packing of acidified foods or thermally processed low-acid foods in hermetically sealed containers are required to register with FDA on Form FDA 2541 within 10 days of so engaging, and to file scheduled processes on Forms FDA 2541a, or 2541c within 60 days of registration and prior to the packing of a new product. This timing for reporting assures against improperly or inadequately processed or packed acidified foods or thermally processed low-acid foods in hermetically sealed containers being introduced into interstate commerce and becoming a public health threat to

the nation.

7. Special Circumstances

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. Outside Consultation

The following consultations are representative of ongoing contacts with persons outside the agency:

January 2003, 2004

Processing Filing Seminar
Better Process Control School
Jamaica, West Indies

Purpose: Discuss process filing requirements

Participants: Industry/Government

FDA: Dennis M. Dignan, Ph.D., CFSAN

May 2002, 2003, 2004

Processing Filing Seminar
Better Process Control School
Bangkok, Thailand

Purpose: Discuss process filing requirements

Participants: Industry/Government

FDA: Dennis M. Dignan, Ph.D., CFSAN

August 2003

Processing Filing Seminar
Better Process Control School
Puebla, Mexico

Purpose: Discuss process filing requirements

Participants: Industry/Government

FDA: Dennis M. Dignan, Ph.D., CFSAN

October 2003

Processing Filing Seminar
FDA Embassy Presentations
Washington, DC

Purpose: Discuss process filing requirements

Participants: Industry/Government

FDA: Dennis M. Dignan, Ph.D., CFSAN

October 2003

Pickle Packers International
Annual Meeting
New Orleans, LA

Purpose: Discuss process filing requirements

Participants: Industry/Government

FDA: Stephen H. Spinak, CFSAN

November 2003

Processing Filing Seminar
Better Process Control School
Pamplona, Spain

Purpose: Discuss FDA's latest position on non-thermal methods of processing food and implementation of the Bioterrorism Act of 2002

Participants: Industry/Government

FDA: Susan J. Brecher, CFSAN

June 2004

Campden & Chorleywood Food Research Association's 3rd International Thermal Processing Conference
Chipping, Campden, England

Purpose: Discuss foreign low acid and acidified foods program including temperature distribution testing or the lack of it and acidification failures - procedural and analytical.

Participants: Industry/Government

FDA: Susan J. Brecher, CFSAN

In the Federal Register of February 7, 2005 (70 FR 6445), FDA published a notice soliciting comments on the information collection. No comments were received.

9. Gifts

There are no payments or gifts to respondents.

10. Confidentiality

All production records and inspection reports collected by FDA are maintained in FDA District Compliance files which have limited access. The food processing information contained on Forms FDA 2541a and FDA 2541c is privileged and confidential. The process filing information is safeguarded in locked files at the Center for Food Safety and Applied Nutrition, FDA, and are accessible only to properly authorized FDA and contractor personnel. These materials are kept confidential in accordance with 21 U.S.C. 331(j).

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Respondent Hour Burden

The annual burden for this information collection is 1,985,108 hours.

A. Reporting

There are approximately 2,487 respondents, new registrants and previously registered "in-business" firms, which are expected to submit a total of 17,586

responses (585 new plant registrations and 17,001 process filing forms) on an annual basis.

The reporting burden for 21 CFR 108.25 (d) and 108.35 (d) and (e) is insignificant because notification of spoilage, process deviation or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and are, therefore, not required to report the occurrence.

No burden has been estimated for the disclosure requirements in sections 113.60(c) and 114.80(b) (21 CFR 113.60(c) and 114.80(b)) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

B. Recordkeeping

There are approximately 7,915 food processing establishments both foreign and domestic registered as processors of acidified foods or thermally processed low-acid foods in hermetically sealed containers. Four FDA staff persons who are experienced in actual food processing plant operations and familiar with the regulations reviewed the recordkeeping procedures used by the industry.

Standardized time frame requirements for conducting the recordkeeping procedures do not exist but it is estimated to take 250 hours per establishment to comply with the recordkeeping requirements in 21 CFR 108, 113, and 114. This compares satisfactorily when based upon firsthand food processing plant experience, individual estimates of the time frames and the frequency of recordkeeping. To avoid double-counting, estimates for 21 CFR 108.25(g) and 108.35(h) have not been included because they merely cross reference recordkeeping requirements contained in parts 113 and 114.

The burden estimates of complying with information collection requirements for OMB No. 0910-0037 are shown below:

Estimated Annual Reporting Burden						
Form No.	CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2541 (Registration)	108.25 and 108.35	585	1	585	.17	99
Form FDA 2541a (Process Filing)	108.25 and 108.35	1,778	9	16,002	.333	5,329
Form FDA 2541c (Process Filing)	108.35	124	10	1240	.75	930
Total						6,358

Estimated Annual Recordkeeping Burden					
CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record keeper	Total Hours
21 CFR Parts 113, 114	7915	1	7,915	250	1,978,750

The estimated annualized cost to respondents for the hour burden for this collection of information is 1,985,108 total annual burden hours x $27.50/hour = $54,590,470.

13. Estimated Costs Burden to Respondents

There are no capital or operation and maintenance cost associated with this collection.

14. Annualized Costs to Government

The annualized costs to the Federal government are $787,216. Approximately 1.5 person years (PY) are expended by food technologists for technical review of the process filing forms (FDA 2541a and 2541c). 2.5 PY are expended for

administration, coordination and computer programming, and a contract was awarded to provide new system development, computer data entry and administrative support (filing, mail handling) to the project. The cost of the contract is $220,832 per year. The estimated annual cost of printing forms and instructions is $5,000.00.

The annual burden for on-site review of the manufacturers records is approximately 2 hours at $60.39 an hour or $120.77 for on-site records inspection. A total of 360 inspections were performed per year for a total cost of $43,478. The burden for the review of records which have been copied and forwarded to CFSAN because of potential problems is approximately 6 hours at $60.39 an hour or $362.32. Records for 35 inspections reviewed by CFSAN cost $12,682. The total cost for FDA inspection and review is $56,160.

One person year (PY) for a fully supported FDA employee equals 2080 hours at a cost of $125,603. The estimated costs incurred by the Government are listed below:

o Contract (annual expense)	$220,832
o Food Technologists - 1.5 PY	$208,136
o Technicians - 2.5 PY	$245,250
o Printing	$ 5,000
o On-site Inspections	$ 43,478
o Records Inspections	$ 12,682
Total	$735,378

15. Changes in Burden

The increase of 482,278 burden hours is due to an increase in the number of respondents who report on an annual basis. Industry growth due to free trade agreements and access to U.S. markets has led to the registration of 585 new plants and a dramatic expansion in the number of respondents. There have been no new reporting and recordkeeping requirements since the last evaluation.

16. Statistical Analysis, Publication Plans, and Schedule

The information obtained from this data collection will not be published.

17. Approval Not to Display Expiration Dates

No approval requested.

18. Exception to Certification Statement

No exceptions requested.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.